UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

James Alley, Ronnie Billings, Sr., Edrick Brown, Geneva Bryant, Waddell Bynun, Jr., Vanessa Covington, Amanda Daniels, George Daniels, Jr., David Glenn, Russell Gray, Ronnie Hair, Thomas Harris, Damien Hollie, Roy Hunt, Wole Iluyomade, Mary Jenkins, Romona Jessie, Joseph Jordan, Paul Lee, Martin Lefever, George Lloyd, James Lyons, Katherine Mileski, Belinda Mobley, Veronica Pendergrass, Micheala Piedra, Linda Pressley, Wanda Puryear, Wanda Reid, Reba Slade, Henry Stanback, Sandra Sweat, Edith Thomas, Carol Williams, Annis Wilson, Norman Wynne, Plaintiffs	§
V.	§ Civil Action No. 06-889 RHK/AJB
ELI LILLY AND COMPANY, Lilly Corporate Center Indianapolis, IN 46285 Defendant	§**COMPLAINT AND** §**DEMAND FOR JURY TRIAL**

I. INTRODUCTION

1. Plaintiffs, by undersigned counsel, hereby institute this Complaint against Eli Lilly and Company ("Defendants"). This case involved the anti-psychotic drug olanzapine (also known herein as "Zyprexa"), designed, formulated, promoted, sold and distributed by Defendants in the United States. Zyprexa caused a high incidence of diabetes, hyperglycemia, pancreatitis, keto-acidosis, and diabetic coma, as well as other severe and permanent injuries.

II. JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because Plaintiffs are citizens of various states which are different from the State where the defendant is incorporated and has its principal places of business, and the amount in controversy, exclusive of interest and costs, exceeds seventy-five thousand dollars ($75,000.00). These claims are subject to Zyprexa Liability Litigation (MDL 1596) assigned to the Honorable Jack B. Weinstein, United States District Court for the Eastern District of New York.

3. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because Eli Lilly sells and distributes its products, including Zyprexa, in Minnesota, and as such has purposely availed itself of the privilege of conducting activities within Minnesota. Eli Lilly thus conducted substantial business in this District and is amenable to suit here.

III. PARTIES.

4. Plaintiff James Alley is a resident of North Carolina and was injured as a result of taking Zyprexa.

5. Plaintiff Ronnie Billings, Sr. is a resident of North Carolina and was injured as a result of taking Zyprexa.

6. Plaintiff Edrick Brown is a resident of North Carolina and was injured as a result of taking Zyprexa.

7. Plaintiff Geneva Bryant is a resident of North Carolina and was injured as a result of taking Zyprexa.

8. Plaintiff Waddell Bynun, Jr. is a resident of North Carolina and was injured as a result of taking Zyprexa.

9. Plaintiff Vanessa Covington is a resident of North Carolina and was injured as a result of taking Zyprexa.

10. Plaintiff Amanda Daniels is a resident of North Carolina and was injured as a result of taking Zyprexa.

11. Plaintiff George Daniels, Jr. is a resident of North Carolina and was injured as a result of taking Zyprexa.

12. Plaintiff David Glenn is a resident of North Carolina and was injured as a result of taking Zyprexa.

13. Plaintiff Russell Gray is a resident of North Carolina and was injured as a result of taking Zyprexa.

14. Plaintiff Ronnie Hair is a resident of North Carolina and was injured as a result of taking Zyprexa.

15. Plaintiff Thomas Harris is a resident of North Carolina and was injured as a result of taking Zyprexa.

16. Plaintiff Damien Hollie is a resident of North Carolina and was injured as a result of taking Zyprexa.

17. Plaintiff Roy Hunt is a resident of North Carolina and was injured as a result of taking Zyprexa.

18. Plaintiff Wole Iluyomade is a resident of North Carolina and was injured as a result of taking Zyprexa.

19. Plaintiff Mary Jenkins is a resident of North Carolina and was injured as a result of taking Zyprexa.

20. Plaintiff Romona Jessie is a resident of North Carolina and was injured as a result of taking Zyprexa.

21. Plaintiff Joseph Jordan is a resident of North Carolina and was injured as a result of taking Zyprexa.

22. Plaintiff Paul Lee is a resident of North Carolina and was injured as a result of taking Zyprexa.

23. Plaintiff Martin Lefever is a resident of North Carolina and was injured as a result of taking Zyprexa.

24. Plaintiff George Lloyd is a resident of North Carolina and was injured as a result of taking Zyprexa.

25. Plaintiff James Lyons is a resident of North Carolina and was injured as a result of taking Zyprexa.

26. Plaintiff Katherine Mileski is a resident of North Carolina and was injured as a result of taking Zyprexa.

27. Plaintiff Belinda Mobley is a resident of North Carolina and was injured as a result of taking Zyprexa.

28. Plaintiff Veronica Pendergrass is a resident of North Carolina and was injured as a result of taking Zyprexa.

29. Plaintiff Micheala Piedra is a resident of North Carolina and was injured as a result of taking Zyprexa.

30. Plaintiff Linda Pressley is a resident of North Carolina and was injured as a result of taking Zyprexa.

31. Plaintiff Wanda Puryear is a resident of North Carolina and was injured as a result of taking Zyprexa.

32. Plaintiff Wanda Reid is a resident of North Carolina and was injured as a result of taking Zyprexa.

33. Plaintiff Reba Slade is a resident of North Carolina and was injured as a result of taking Zyprexa.

34. Plaintiff Henry Stanback is a resident of North Carolina and was injured as a result of taking Zyprexa.

35. Plaintiff Sandra Sweat is a resident of North Carolina and was injured as a result of taking Zyprexa.

36. Plaintiff Edith Thomas is a resident of North Carolina and was injured as a result of taking Zyprexa.

37. Plaintiff Carol Williams is a resident of North Carolina and was injured as a result of taking Zyprexa.

38. Plaintiff Annis Wilson is a resident of North Carolina and was injured as a result of taking Zyprexa.

39. Plaintiff Norman Wynne is a resident of North Carolina and was injured as a result of taking Zyprexa.

40. Eli Lilly and Company (hereinafter referred to as "Defendant" or "Lilly") is a corporation incorporated under the laws of the State of Indiana with its principal place of business in Indiana.

41. Defendant is, and was at all relevant times, duly authorized to conduct business in the State of Minnesota.

42. Defendant has transacted business in the State of Minnesota.

43. Defendant regularly conducts and solicits business within the State of Minnesota.

44. At all relevant times, Defendant, through its agents, servants, and employees, was the designer, manufacturer, marketer, advertiser, distributor, and seller of Zyprexa and Zyprexa Zydis, also known as olanzapine (hereinafter individually and collectively referred to as "Zyprexa").

45. Defendant, either directly or through its agents, servants, and employees, does business in the State of Minnesota, and at all relevant times, has sold and distributed Zyprexa in the State of Minnesota for use in the treatment of schizophrenia, bipolar disorder, and other "off-label" uses.

46. Defendant derives substantial revenue from goods used or consumed in the State of Minnesota.

47. Defendant expected, or should have expected, that its actions could or would have consequences within the State of Minnesota.

IV. NATURE OF THE CASE

48. Defendant, either directly or through its agents, servants, and employees, designed, manufactured, marketed, advertised, distributed, and sold Zyprexa for the treatment of schizophrenia, bipolar disorder, as well as other "off-label" uses.

49. As a result of the defective nature of Zyprexa, those persons who were prescribed and ingested or injected Zyprexa, including Plaintiffs, have suffered and may continue to suffer severe and permanent personal injuries, including the

development of diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent injuries.

50. Defendant concealed its knowledge of Zyprexa's unreasonably dangerous risks from Plaintiffs, other consumers, and the medical and psychiatric communities.

51. Defendant failed to conduct adequate post-marketing surveillance of Zyprexa after it began marketing, advertising, distributing, and selling the product.

52. Consequently, Plaintiffs seek compensatory damages as a result of their injuries resulting from their ingestion of Zyprexa, which has caused and will continue to cause Plaintiffs to suffer pain, mental anguish, and other injuries, and to incur significant medical and related expenses.

FACTUAL BACKGROUND

53. At all relevant times, Defendant has been responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling Zyprexa.

Zyprexa's FDA History

54. In 1996, the United States Food & Drug Administration ("FDA") approved Zyprexa for use for the treatment of schizophrenia.

55. In 2000, the FDA approved Zyprexa for use for the short-term treatment of acute mixed or manic episodes associated with bipolar disorder.

56. In 2004, the FDA approved Zyprexa for maintenance in the treatment of bipolar disorder, also known as manic-depressive illness.

Defendant Has Realized Significant Profits from Sales of Zyprexa

57. Zyprexa is one of Defendant's top-selling drugs.

58. Since Defendant introduced Zyprexa in 1996, it has been prescribed to more than 12 million people worldwide.

59. In 2003, approximately seven million prescriptions for Zyprexa were dispensed resulting in more than $2 billion in sales. In 2003, Zyprexa was the seventh largest selling drug in the country by retail sales.

60. Zyprexa is an atypical antipsychotic medication. Zyprexa, like other antipsychotic medications, may improve symptoms associated with schizophrenia and bipolar disorder such as agitation, delusions, hallucinations, and suspiciousness.

61. Consumers, including Plaintiffs, who have used, and in some instances continue to use Zyprexa, have available several alternative atypical antipsychotic medications including Abilify, Risperdal, Clozaril, Seroquel, and Geodon, as well as other antipsychotic medications, including Haldol, Thorazine, Prolixin, Navane, Stelazine, Trilafon, and Mellaril.

62. In December 2000, the *British Medical Journal* found no clear evidence that Zyprexa or other atypical antipsychotics were more effective or better tolerated than conventional antipsychotics including Haldol and Thorazine.

63. In November 2003, the *Journal of the American Medical Association* compared Zyprexa with Haldol and found "no statistically or significant advantages" of Zyprexa for treatment of schizophrenia. The authors did note a significant difference among the costs of Haldol and Zyprexa per tablet: $0.02 versus $4.84 respectively.

Zyprexa's Association With Diabetes and Other Serious Injuries

64. Shortly after Defendant began selling Zyprexa, reports of consumers who were using Zyprexa suffering from hyperglycemia, acute weight gain, exacerbation of diabetes mellitus, pancreatitis, and other severe diseases and conditions associated began to surface. Defendant knew, or was reckless in not knowing, of these reports. Furthermore, Defendant has been aware of studies and journal articles linking use of Zyprexa with these and other severe and permanent diseases since 1998.

65. Diabetes is associated with long-term complications that affect nearly every part of the body. Diabetes often leads to blindness, heart and blood vessel disease, strokes, kidney failure, amputations, and nerve damage.

66. Between April 1996 and May 2001, the FDA received several reports of hyperglycemia, worsening of existing diabetes, pancreatitis, and other severe injuries among children who were prescribed Zyprexa.

67. Beginning in 1998, scientific journals began to publish studies that suggested a causal association between using Zyprexa and developing or exacerbating diabetes mellitus (hereinafter "diabetes") and development of dangerously high blood sugar levels, *i.e.*, hyperglycemia.

68. As early as 1998, the worldwide pharmacology and epidemiology department at Eli Lilly began receiving adverse event reports revealing excessive weight gain as well as reports for diabetes mellitus, ketoacidosis, and increased incidents of hyperglycemia, in patients taking Zyprexa. These reports were consistent with reports provided to Eli Lilly prior to the launch of the drug which warned against a risk of "significant weight gain and Type II Diabetes." Eli Lilly disregarded these early warnings, and pressed ahead with the launch of the drug.

69. In its clinical trial, Eli Lilly denied that any patient using Zyprexa developed diabetes due to weight gain with the drug.

70. As early as January, 2000, Eli Lilly continued to market and promote the drug minimizing the weight gain problem, while it continued to receive reports which proved that Zyprexa had a strong association with excessive weight gain and diabetes. In fact when questioned by the FDA in May, 2000, Eli Lilly refused to disclose to the FDA that Zyprexa caused a significant increase in blood glucose, which its own investigation had revealed.

71. In November 2001, the *Journal of the American Medical Association* reported a link between the use of Zyprexa by adolescents and development of hyperglycemia.

72. Recently, studies conducted in Europe and Japan revealed that numerous patients treated with Zyprexa experienced a significantly higher incidence of severe and permanent diseases and conditions, including dangerous rises in blood glucose levels.

73. In July 2002, a study conducted at Duke University further established a relationship between Zyprexa and diabetes. This study documented nearly 300 cases of diabetes among people using Zyprexa.

74. In April 2002, the British Medicines Control Agency warned about the risk of diabetes for patients prescribed Zyprexa in its newsletter *Current Problems in Pharmaco-vigilance*. This newsletter reported forty (40) reports of diabetes, hyperglycemia, diabetic ketoacidosis, diabetic coma, and one death among users of Zyprexa. Subsequently, the British government required Defendant to warn consumers

about the risk of diabetes and diabetic ketoacidosis, and to further required Defendant to instruct patients who were using Zyprexa to monitor their blood sugar levels.

75. In April 2002, the Japanese Health & Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and diabetic coma for patients prescribed Zyprexa.

76. In July, 2003, the FDA placed Eli Lilly on notice that it was going to require Eli Lilly to add metabolic disorders, such as diabetes and ketoacidosis, associated with Zyprexa to the warning section of the label in the United States. This notice came after Eli Lilly was already aware that Zyprexa was associated with diabetes. Indeed, by the time the FDA placed Eli Lilly on notice in 2003, Eli Lilly was fully aware of the risk of diabetes, and had implemented a marketing plan to mislead and misinform physicians about the known risks associated with the drug.

77. Finally, in March, 2004, eleven months after Eli Lilly was first notified by the FDA and eight months after the FDA's formal request for a label change, Eli Lilly updated the Zyprexa label to add warnings regarding diabetes and other metabolic disorders.

78. The physicians who prescribed Zyprea to Plaintiffs relied on the representations made to them by the Defendant prior to the date of prescribing Zyprexa for use. The physicians relied on the representations regarding the safety of Zyprexa, and would not have recommended for use or prescribed Zyprexa if they had known the true facts regarding the safety of Zyprexa.

79. Prior to the date upon which the drug was prescribed to Plaintiffs, the Defendant knew, or should have known, that the product was extremely dangerous

and unsafe for use by the general public for the aforesaid purpose. The dangers of this product included, by way of example, the likelihood of developing hyperglycemia, pancreatitis, diabetes or ketoacidosis and other injuries. The Defendant failed to take appropriate action to cure the nature of these defects or to warn users of the product or their physicians of such dangerous characteristics.

80. As such, Defendant did not adequately warn consumers in this country, including Plaintiffs, about the risk of diabetes, hyperglycemia, diabetic ketoacidosis, or other serious injuries caused by Zyprexa, until March of 2004.

81. Defendant misrepresented and failed to appropriately warn consumers, including Plaintiffs, and the medical and psychiatric communities, of the dangerous risk of developing diabetes, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences caused by Zyprexa, and consequently placed its profits above the safety of its customers.

82. By reason of the foregoing, Plaintiffs have developed diabetes, and/or pancreatitis and are at an increased risk of developing pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent injuries.

83. By reason of the foregoing, Plaintiffs have been severely and permanently injured and will require constant and continuous medical care and treatment.

FRAUDULENT CONCEALMENT

84. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiffs and their prescribing physician the true risks associated with taking Zyprexa.

85. As a result of Defendant's actions, Plaintiffs and their prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that they had been exposed to the risks alleged herein, and that those risks were the direct and proximate result of Defendant's acts and omissions, until March of 2004.

COUNT I

STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

86. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

87. Defendant, as the manufacturer and supplier of Zyprexa, failed to provide proper warnings to physicians regarding all possible adverse side effects regarding the use of Zyprexa, as well as the severity and duration of such adverse effects.

88. Defendant failed to perform adequate testing that would have shown that Zyprexa possessed serious potential side effects with respect to which full warnings were needed.

89. Defendant failed to conduct adequate post-marketing warning and instruction because, after Defendant knew or should have known of the risk of injury and death from Zyprexa, Defendant failed to provide adequate warnings to physicians, and continued to aggressively promote Zyprexa.

90. As the direct and legal result of the defective condition of Zyprexa:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity.

COUNT II

STRICT PRODUCTS LIABILITY (DESIGN DEFECT)

91 Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

92 Zyprexa is defectively designed because the foreseeable risks exceeded the benefits associated with the design or formulation.

93 Additionally, Zyprexa is defective due to inadequate clinical trials, testing, study, and inadequate reporting regarding the results of same.

94. As the direct and legal result of the defective condition of Zyprexa:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity;

c. Plaintiffs expended, and may in the future be required to expend, fair and reasonable expense or necessary health care, attention and services and incurred incidental and related expenses.

COUNT III

NEGLIGENT FAILURE TO WARN

95. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege:

96. Zyprexa was not accompanied by appropriate warnings of the increased risk of adverse side effects caused by the ingestion of Zyprexa.

97 Defendants negligently failed to warn consumers who took Zyprexa that it was dangerous.

98. Defendants negligence was the proximate cause of the harm suffered by Plaintiffs.

99. As a direct and proximate cause of Defendants' negligence:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of earnings and loss of earning capacity;

c. Plaintiffs expended, and will in the future be required to expend, fair and reasonable expenses for necessary health care, attention and services and incurred incidental and related expenses.

COUNT IV

NEGLIGENCE PER SE

100. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

101. Defendant was negligent per se because it violated applicable statutes and regulations relating to prescription drugs. Plaintiffs are people whom these statutes and regulations were meant to protect.

102. Defendant's negligence was the proximate cause of the harm suffered by Plaintiffs.

103. As a direct and proximate cause of Defendants' negligence:

a. Plaintiffs suffered personal injuries;

b. Plaintiffs suffered economic loss, including loss of Earnings and loss of earning capacity;

c. Plaintiffs expended, and will in the future be required to

expend, fair and reasonable expenses for necessary health care, attention and services and incurred incidental and related expenses

COUNT V

BREACH OF IMPLIED WARRANTY

104. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

105. Defendant breached the implied warranty of merchantability because Zyprexa cannot pass without objection in the trade, is unsafe, not merchantable, and unfit for its ordinary use when sold, and is not adequately packaged and labeled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter a judgment against Defendant and in favor of Plaintiffs and award the following relief:

1. Declare that Zyprexa is dangerous and defective;
2. Compensatory damages awarded on behalf of Plaintiffs against Defendant in an amount deemed appropriate by their trier of fact to compensate Plaintiffs for physical and emotional pain and suffering as well as for Plaintiffs actual damages, including but not limited to, medical, incidental, hospital, and service expenses, and loss of earnings and earning capacity;
3. Prejudgment and post judgment interest on all damages as is allowed by the law;
4. Past and future mental and emotional distress damages;
5. Costs, including expert fees and attorneys' fees and expenses, and costs

incurred in the prosecution of this action; and,

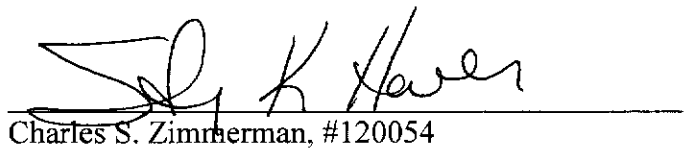
6. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: 2/27, 2006

ZIMMERMAN REED, P.L.L.P.



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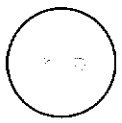

ZIMMERMAN REED
ATTORNEYS AT LAW

44952

February 27, 2006

STACY K. HAUER
Admitted in Minnesota
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REPLY TO MINNEAPOLIS

Richard D. Sletten
Clerk of Court
United States District Court
District of Minnesota
300 South Fourth Street
Minneapolis, MN 55415

RE: James Alley, et al. v. Eli Lilly and Company

Dear Mr. Sletten:

Enclosed for filing in the above-referenced matter, please find the following:

1. Civil Cover Sheet;
2. Summons;
3. Complaint; and

Please file-stamp Summons and Complaint and return to our office via the messenger so that I may effectuate service upon Defendants. Also enclosed please find a check in the amount of $250.00, representing the filing fee.

Very truly yours,

ZIMMERMAN REED, P.L.L.P.

Stacy K. Hauer

SKH:cav
Enclosures

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